MAY 1 0 2004

K040473

SECTION E
510(k) SUMMARY – Revised May 4, 2004

1. SUBMITTER INFORMATION:

Name:	NovaMin Technology, Inc.
Address:	13709 Progress Blvd., #23 Alachua, Florida 32615 USA
Phone:	(386) 418-1551
Facsimile:	(386) 418-1465
Contact:	David C. Greenspan, Ph.D.
Preparation Date:	February 23, 2004

2. DEVICE NOMENCLATURE:

Trade Name:	Oravive™ Tooth Revitalizing Paste
Common Name:	Dentifrice, Toothpaste
Classification Name:	Agent, Polishing, Abrasive, Oral Cavity

3. LEGALLY MARKETED PREDICATE DEVICE:

Device Name:	Butler GUM® Prophylaxis Paste with NovaMin®
510(k) Number:	K024343
Applicant:	USBiomaterials Corporation

4. DEVICE DESCRIPTION:

Oravive™ is a daily-use, fluoride-free toothpaste device that incorporates NovaMin® as its active ingredient. The non-aqueous formulation is designed to clean your teeth as well as give your whole mouth a fresh feeling we call REVITALIZING! Oravive™ is also designed to physically occlude dentin tubules for the management of sensitive teeth. NovaMin® (calcium sodium phosphosilicate) is composed of elements that occur naturally in the body (Ca, Na, Si, P, and O). When exposed to an aqueous environment, NovaMin® undergoes a rapid surface reaction, allowing it to physically occlude tubules. Within a short period of time, essentially all of the NovaMin® reacts to form hydroxycarbonate apatite (HCA), which is chemically and structurally similar to natural tooth mineral.

5. INTENDED USE:

Oravive™ is a fluoride-free toothpaste product intended for cleaning the tooth surface on a daily basis. Clinical studies have shown that Oravive™ also provides relief from tooth sensitivity due to cold, heat, acids, sweets, or contact by the occlusion of dentin tubules.

6. TECHNOLOGICAL CHARACTERISTICS:

The technological characteristics of Oravive™ and Butler GUM® Prophylaxis Paste with NovaMin® are very similar. Both devices are designed to relieve hypersensitivity associated with exposed dentin by the deposition of a calcium phosphate layer onto the tooth surface. Both devices use NovaMin® to produce a calcium phosphate layer that occludes dentinal tubules and blocks hydrodynamic flow. The primary difference between the two devices is that Oravive™ supplies the calcium and phosphate ions on a daily basis, whereas Butler GUM® Prophylaxis Paste with NovaMin® supplies the ions once every professional tooth cleaning. In addition, there are some differences in the proportion of the ingredients in the two products.

7. SAFETY AND PERFORMANCE DATA:

Many different biocompatibility tests have been performed on NovaMin®, the active ingredient in Oravive™. The results of these tests indicate that there is no evidence of any hazardous effects to the patient if the product is used as directed.

The tubule occlusion efficacy of Oravive™ was evaluated using an *in vitro* dentin block model. The results indicate that Oravive™ occludes a statistically significant number of tubules when compared to controls.

The relative abrasion level of Oravive™ was evaluated at Indiana University School of Dentistry. The procedure used was the ADA recommended procedure for determination of toothpaste abrasivity. The result was a mean Relative Dentin Abrasivity (RDA) value of 125.55. This RDA value is well under the limit considered safe for daily-use (RDA value < 250).

A randomized, double-blind, placebo-controlled, six-week clinical trial was conducted to evaluate the efficacy of Oravive™ Tooth Revitalizing Paste with a placebo and a commercially available $SrCl_2$ desensitizing toothpaste. The study was approved by the Medical Ethics Committee of the School of Stomatology, Wuhan University, Wuhan, China. Written informed consent and medical history were obtained prior to entering patients into the study. A total of seventy-five (75) patients were accepted into the study; twenty-five (25) in each group. There were no significant differences in the average ages between the test groups. Brushing regimen was twice daily for a six-week period. Tooth sensitivity was recorded by marking the degree of discomfort experienced by the patient on a 10cm visual analog scale (VAS) after stimulation of selected teeth by cold water and a metered air blast. The results were analyzed for statistical significance using ANOVA and Bonferonni *post hoc* tests.

Sixty-seven (67) patients completed the six-week study. No adverse events in any of the groups were reported. The results showed that the mean values of the VAS scores resulting from the air stimulus and cold water were reduced significantly ($p < .01$) in both the test and positive control groups compared with the placebo group after six weeks of tooth brushing. Reduction in VAS for the NovaMin® containing toothpaste at six weeks was 36% for the air stimulus and 39% for the cold water stimulus.

The results of this study showed that the NovaMin® containing toothpaste reduced dentin sensitivity significantly over a six-week time period, and that it performed equivalently to a $SrCl_2$ containing, commercially available desensitizing toothpaste.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 0 2004

Dr. David C. Greenspan
Vice President & Chief Technology Officer
NovaMin Technology, Incorporated
13709 Progress Boulevard #23
Alachua, Florida 32615 USA

Re: K040473
Trade/Device Name: Oravive™ Tooth Revitalizing Paste
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: NRE
Dated: February 23, 2004
Received: February 24, 2004

Dear Dr. Greenspan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION D
STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K040473

Device Name: Oravive™ Tooth Revitalizing Paste

INDICATIONS FOR USE:

Oravive™ is a fluoride-free toothpaste product intended for cleaning the tooth surface on a daily basis. Clinical studies have shown that Oravive™ also provides relief from tooth sensitivity due to cold, heat, acids, sweets, or contact by the occlusion of dentin tubules.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040473

Prescription Use _____ OR (Per 21 CFR 801.109) Over-The-Counter Use X